

REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

Claims 3 and 7 are amended to further define the polynucleotides and polypeptides encoded thereby, consistent with the language suggested by the Examiner. These amendments do not contain any new matter as they are fully supported by the specification and the claims as originally filed.

It is respectfully submitted that entry of the amendments submitted herewith is proper because these amendments place the present application in condition for allowance or at a minimum, in better condition for appeal. Accordingly, entry of the amendments submitted herewith is respectfully requested.

Upon entry of this Amendment, claims 3-11 will remain pending in the application. A detailed listing of all claims that are, or were, in the application, irrespective of whether a particular claim remains under examination in the application, is presented, beginning on page 2 of this paper under "Listing of Claims," with an appropriate defined status identifier.

III. Response to Issues Raised by Examiner in Outstanding Office Action

A. Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 3-11 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse this ground for rejection.

The Examiner asserts that "[i]t is unclear what sequences are encompassed by 'at least about 95% identity'" (Office Action, page 2). It is respectfully submitted that one of skill in the art would readily understand the claims as written. However, in efforts to reduce the issues and expedite prosecution, claims 3 and 7 are amended herein consistent with the

language suggested by the Examiner. Thus, claims 3 and 7, as currently amended, recite “at least 95% sequence identity.”

Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

B. Claim Rejections – 35 U.S.C. § 101

Claims 3-11 are rejected by the Examiner under 35 U.S.C. § 101 for allegedly lacking either a specific, substantial and credible asserted utility, or a well established utility. Applicants respectfully traverse this ground for rejection.

The utility requirement may be viewed as requiring: (1) that an application include an asserted utility for the claimed subject matter; and further, (2) that the asserted utility be a substantial and credible utility. Thus, the present specification asserts that MACP-2 is associated with cell proliferation. This asserted utility is “substantial” and “credible.”

1. The claimed invention is supported by an asserted utility.

The specification contains an asserted utility for the claimed invention, as described previously. Specifically, the polynucleotides of the claimed invention are associated with cell proliferation. Furthermore, the Examiner has acknowledged this assertion, that is, “the Office recognizes that Applicant has asserted a utility for the claimed polynucleotides” (Office Action at page 3).

2. The asserted utility is substantial and credible.

As is well appreciated, post-filing evidence may be used to substantiate an asserted utility. As previously noted, subsequent to the filing of the present application, it was confirmed that the polypeptide of SEQ ID NO:2 is associated with cell proliferation. See Wissmann et al., J. Pathology 201:204-12 (hereinafter “Wissmann”) (Copy previously provided).

Wissmann recognized a substantial utility for the polynucleotide encoding MACP-2 by performing their disclosed experiments showing that expression of the polynucleotide encoding MACP-2 is down-regulated at the RNA level in 64% of primary prostate cancers. Furthermore, the asserted utility of SEQ ID NO:2 as associated with cell proliferation is “credible” because this asserted utility was tested and confirmed by Wissmann, who clearly represents those of skill in the art. Thus, Wissmann supports Applicants’ assertion that the asserted utility of the claimed invention is both substantial and credible.

For these reasons, the Applicants have asserted a utility for the claimed subject matter which subsequently has been confirmed by others of skill in the art. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 101 for lack of utility are requested.

C. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph (Enablement)

Claims 3-11 were rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Specifically, in rejecting claims 3-11 under 35 U.S.C. § 101 because the claimed invention allegedly lacks utility, the Examiner asserts that “one skilled in the art clearly would not know how to use the claimed invention” (Office Action at page 7). Applicants respectfully traverse this ground for rejection.

Based on the arguments in the preceding section, the application supports an asserted substantial and credible utility for the claimed polynucleotides and therefore, the rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement has been rendered moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

D. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph (Written Description)

Claims 3-11 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Applicants respectfully traverse this ground for rejection for at least the reasons already of record.

Specifically, the present specification satisfies the written description requirement as detailed in Example 14 of USPTO's "Synopsis of Application of Written Description Guidelines" and summarized by the Examiner in the Office Action at page 8,

...a single species was deemed representative of the genus because (1) all members have at least 95% structural identity with the reference sequence, and (2) because of the present of the assay which applicant provided for identifying all of the at least 95% identical variants which have the specified function.

Applicants respectfully disagree with the Examiner's assertion that Applicants have not met either criteria. To the contrary, the present specification satisfies both of the above enumerated requirements.

Specifically, with respect to requirement (1), claims 3 and 7 (from which the remainder of the claims depend), as amended herein, recite "at least 95%" sequence identity to reference sequences SEQ ID NO:2 and SEQ ID NO:7, respectively. Thus, it is indisputable that these claims satisfy this requirement.

With respect to requirement (2), claims 3 and 7, recite a "polypeptide associated with cell proliferation." Accordingly, contemplated variant polynucleotides can be assayed for association with cell proliferation by any of a number of methods described in the application and well-known to those in the art. For example, expression of polynucleotides having at least 95% sequence identity to SEQ ID NO:7 can be assayed using Northern blot or microarray analysis of proliferating cells or cells exhibiting a proliferative disorder and compared to expression in matched normal cells. Differential expression in proliferating cells would indicate an association with cell proliferation. Guidance for these methods can be found in the specification at for example, Example IV (pages 41-42) and Example VII (pages 44-45). In addition these methods are well known in the art. Thus, this second requirement is satisfied.

Based on the above, the written description requirement is fully satisfied for the scope of claims 3-11, as amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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